#### Citation:

Payette H, Coulombe C, Boutier V, Gray-Donald K. Weight loss and mortality among free-living frail elders: a prospective study. *J Gerontol A Biol Sci Med Sci.* 1999;54(9):M440-M445.

**PubMed ID: 10536646** 

# **Study Design:**

Prospective Cohort Study

#### Class:

B - <u>Click here</u> for explanation of classification scheme.

# **Research Design and Implementation Rating:**



POSITIVE: See Research Design and Implementation Criteria Checklist below.

# **Research Purpose:**

To evaluate the impact of nutritional risk factors on mortality in a frail elderly population receiving home help services.

#### **Inclusion Criteria:**

Subjects were able to answer the interviewer's questions and provide a 24-hour dietary recall and informed consent.

#### **Exclusion Criteria:**

There were no exclusion criteria; however, a number of subjects (12%) were not asked to participate if, according to the home care team, their physical or mental health could be perturbed or worsened by the interview.

# **Description of Study Protocol:**

#### Recruitment

Subjects were recruited through home care program from six local community service centers in the area of Sherbrook, Canada.

Design: Prospective cohort study

Blinding used (if applicable): not described

Intervention (if applicable): not described

**Statistical Analysis** 

- Seven subjects who died within 90 days of the baseline interview were excluded from the analyses, so that acute conditions resulting in early death would not be considered.
- The final analytical cohort comprised 288 elders with a follow-up from the baseline examination (1991-1993) to September 1, 1996 or to death.
- Differences between survivors and deceased characteristics were tested using Student's t test for unpaired data or chi-square test where appropriate.
- Cox's multivariate survival analysis was used to identify independent predictors of mortality.
- The relative risks (RR) and 95% confidence intervals (CI) associated weight loss, low and high BMI compared to normal, a low ratio energy intake and low protein intake were estimated using separate univariate models.

# **Data Collection Summary:**

# **Timing of Measurements**

• Measurements made at baseline and after 3 - 5 years of follow-up

# **Dependent Variables**

- Mortality
- Vital status during follow-up was obtained from each participant's chart in the CLSC along with information from medical, hospital, or nursing home records and surveillance.
- Official certificates were obtained for confirmation of death. Cause-specific mortality was coded using the 9<sup>th</sup> revision of the International Classification of Diseases.

# **Independent Variables**

- Baseline BMI
- Weight loss prior to baseline
- Energy and protein intake
- Voluntary or involuntary weight loss of 1 kg or more during the past year was self-reported by participants.
- Height and weight were measured using standardized procedures and body mass index (BMI) was computed.
- Usual dietary intake was assessed by three nonconsecutive 24-hour recalls
- The adequacy of the energy intake was evaluated by comparing each individual's intake averaged over the three days to their specific Harris-Benedict prediction equation.

#### **Control Variables**

- Age
- Gender
- Smoking
- Health and functional status
- Demographic factors, physical health, and health habits (alcohol use and cigarette smoking) were collected at the time of baseline interview.
- Functional status was determined using valid instruments.

# **Description of Actual Data Sample:**

Initial N: not described. It was noted that 12% were not asked to participate, 9% could not be

reached, and 12% refused to participate.

**Attrition (final N):** 288 (81 men; 207 women). It was noted that participation rate was 67% and loss to follow up was 4%.

Age: mean 78.2±7.6 years

**Ethnicity**: not described. It was noted that 83% of the interviews were conducted in French.

Other relevant demographics: There were no statistical differences between subjects receiving home-delivered meals or home help for meal preparation and the rest of the sample with regards to age and gender.

**Anthropometrics**: There were no statistical differences between subgroups on weight status.

Location: Quebec, Canada

# **Summary of Results:**

# **Key Findings**

- There were 102 deaths (35.4%) during 3.6-63.7 months of follow-up with a mean of 41.1±18.1 months.
- Top two causes of death: 35 cardiovascular events and 14 cancer events.
- Weight loss was significantly (P<.01) more prevalent among those who died than among survivors.
- In multivariate analysis, weight loss at baseline was a significant predictor of mortality, RR=1.76 (95% CI:1.15-2.71), as was male gender, RR=2.71 (95% CI:1.73-4.24), and age at baseline, RR=1.40 (95% CI:1.06-1.86).

# Relative risk estimates derived from Cox's Model with gender, age, and involuntary weight loss as predictors of survival time

Variable		All-Cause	Exclusion of Cancer
		Mortality	Mortality
		RR (95%CI)	RR (95% CI)
Gender	Female	1.0	1.0
	Male	2.71 (1.73-4.24)	2.61 (1.60-4.26)
Age	Baseline	1.4 (1.06-1.86)	1.42 (1.05-1.91)
	1 year later	1.06 (1.02-1.10)	1.06 (1.02-1.11)
	3 year later	1.00 (0.97-1.04)	1.01 (0.97-1.05)
	5 year later	0.98 (0.93-1.03)	0.98 (0.93-1.04)
Weight Loss	No	1.0	1.0
	Yes	1.76 (1.15-2.71)	1.68 (1.06-2.68)

#### **Author Conclusion:**

In this free-living frail elderly population, weight loss is a predictor of early mortality after controlling for smoking, and functional and health status indicators. It needs to be explored in an intervention study whether prevention of weight loss would lead to increased survival.

#### Reviewer Comments:

# Strengths

- Follow-up rate was high enough to minimize the possibility of selection biases.
- Measurements and analyses of food intake and functional status were described adequately and were based on valid instruments.
- Height and weight were measured with a standardized scale to ensure accuracy.
- Adjustments in statistical analysis were made to ensure groups were comparable on a number of potential confounders.

#### Limitations

- The participants were not a representative sample of the general population.
- It was unclear if blinding was used for interviewers and subjects to prevent introduction of
- Study limitations were not identified and discussed.

#### Research Design and Implementation Criteria Checklist: Primary Research

# **Relevance Questions**

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
	,	

2. Did the authors study an outcome (dependent variable) or topic that Yes the patients/clients/population group would care about?

3. Is the focus of the intervention or procedure (independent variable) Yes or topic of study a common issue of concern to nutrition or dietetics practice?

Is the intervention or procedure feasible? (NA for some 4. N/A epidemiological studies)

# **Validity Questions**

1.	Was the	research question clearly stated?	Yes
	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
	1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?		Yes

Yes

	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
	2.2.	Were criteria applied equally to all study groups?	Yes
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
	2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	Were study groups comparable?		
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	d of handling withdrawals described?	Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	Yes
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	g used to prevent introduction of bias?	Yes

	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		vention/therapeutic regimens/exposure factor or procedure and rison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A
	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outco	mes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the star	tistical analysis appropriate for the study design and type of licators?	Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	• •		No
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	No
10.	Is bias due t	to study's funding or sponsorship unlikely?	Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes

Copyright American Dietetic Association (ADA).